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BioTools Announces U. S. Pharmacopeia Publication of New VCD Standard Method for Determining Absolute Configuration of Chiral Molecules

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(Jupiter, FL. April 4, 2017). Vibrational circular dichroism (VCD), an important analytical method for determining the absolute configuration (AC) and purity of chiral molecules, has been published as a new “standard method” in the U. S. Pharmacopeia (USP 39-NF34, Chapters 782 and 1782). The chapters became official on December 1st, 2016.

Over 80% of all new small molecules in development and on the market are chiral, including many of today’s blockbuster drugs such as Lipitor, Plavix, and Nexium. The new standard method dramatically affects the speed with which a drug becomes available: The sooner a specific chiral structure can be defined and the relative ratio of chiral molecules determined, the sooner the drug’s bioactivity can be understood, and the sooner it can come to market, dropping drug costs and, often, saving lives.

Like our right and left hands, chiral molecules are mirror images of each other. These left/right pairs of stereoisomers are called “enantiomers.” Human chemistry, as with all biological organisms, recognizes and responds only to specific chiral patterns (typically just the right or just the left stereoisomer). As a result, chiral molecules control critical biological activities such as metabolism and drug uptake.

The chapters were written by a consortium of scientists from key pharmaceutical companies and the two co-founders of BioTools, VCD experts Dr. Rina K. Dukor and Prof. Laurence A. Nafie. Chapter <782> details aspects of VCD usages including qualification of VCD spectrometers, sample measurements, validation, and verification of measured spectra. Chapter <1782> provides specific examples of instrumentation, finer points of qualitative and quantitative analysis, comparisons between measured and calculated spectra, determination of enantiomeric excess (%EE), and concurrent use of AC and %EE.

Previously, the principal method for determining AC involved growing single crystals of one enantiomeric form then performing a special form of X-ray crystallography. If the chiral molecule is an oil or does not readily form single crystals, this approach is impossible or, at best, time consuming and difficult. In contrast, VCD requires no crystallization or further chemical modification of the molecule and can readily be done in solution. VCD is now used by all of the world's leading pharmaceutical companies, top academic institutions and regulatory agencies. Structures of over 7000 molecules have been determined with VCD and over 150 patents for new drug applications (NDA) have been filed where AC is proven with VCD. The new standardized method can be used to determine AC of active pharmaceutical ingredients (APIs) assuring that the results will be the same no matter which instrument is used.

The new USP Chapters are available in print as well as on-line. Details are available at www.usp.org. For further information on this specific VCD methodology, contact Dr. Rina Dukor at 561.625.0133.

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About BioTools:

BioTools is the recognized leader in advanced chiroptical instrumentation, software, and services. They provide solutions for critical molecular structure characterization, from basic research to finished products, for biopharmaceutical and chiral drug research in both academe and pharma.

Founded in 2000, BioTools has R&D, sales, customer support, contract research lab and manufacturing facilities in Jupiter, Florida, and two divisions, BioTools Europe, headquartered in the United Kingdom and BioTools China. Additionally, they enjoy a partnership with the Ghent University and the University of Antwerp in the commissioned European Centre for Chirality (EC2) (www.chiralitycentre.eu). BioTools' co-founders and products have both been recognized by numerous International Awards.